REMARKS

Claims 41-61 are currently pending in this application, though claims 52-61 have been withdrawn.

Sequence Compliance

In the Office Action dated March 22, 2006, the Office objected to the specification and claim 46 for failing to adhere to the sequence rules. Applicants have amended the specification to include SEQ ID NOS to all mentions of specific sequences in the specification and in the claims. Specifically, Applicants have amended pages 11, 22, 23, 24, and 39, including the legend to Figure 11, to include the SEQ ID NOS of the sequences provided.

Claim Objections

On page 3 of the Office Action, the Office objected to claim 41 because it asserted that the claim refers to polynucleotide segments by their acronyms without identification of the full names. As amended, claim 41 includes the terms "central polypurine tract" and "central terminator sequence" to refer to the terms "cPPT" and CTS," respectively.

The Office also objected to claim 46 because it asserted that the claim refers to Figure 11. As amended, claim 46 does not refer to Figure 11, but instead to the SEQ ID NOS that correspond to the sequences of Figure 11.

In light of these amendments, Applicants respectfully request that the objections to the specification and claims be withdrawn.

Double Patenting

On page 4, the Office rejected claims 41-51 under 35 U.S.C. § 101 because it asserted that these claims are drawn to the same invention as are the claims of U.S. Patent No. 6,682,907. Applicants traverse this rejection. Claim 41, and claims 42-51, which depend on claim 41, are drawn to a recombinant vector comprising a polynucleotide comprising cPPT and a CTS region, wherein the cPPT and CTS "are of retroviral-like origin and derived from a transposon." In contrast, the claims of U.S. Patent No. 6,682,907 are drawn to a recombinant vector comprising a polynucleotide containing a cPPT and CTS regions which are of "retroviral-like origin." Therefore, the claims of the instant application are of a different scope than are those of U.S. Patent No. 6,682,907 and, thus, do not claim the same invention as the claims of that patent. Accordingly, Applicants request that the statutory double-patenting rejection in light of U.S. Patent No. 6,682,907 be withdrawn.

Also on page 4 of the Office Action, the Office provisionally rejected claims 41-51 under 35 U.S.C. § 101 because the Office asserted that these claims are drawn to the same invention as are claims 1, 3, 4, 9-14, 20, 27, and 33 of co-pending Application No. 10/313,038. Applicants traverse this rejection noting that claims 1-35 were canceled in a Preliminary Amendment filed on September 30, 2003, for that application.

In addition, on pages 5-7 of the Office Action, the Office made non-statutory obviousness-type double patenting rejections. First, the Office asserted that claim 43 is unpatentable over claim 7 of U.S. Patent No. 6,682,907, in view of Naldini *et al.* (1996). In addition, the Office asserted that claim 41 is unpatentable over claim 2 of the same patent. Applicants are submitting herewith a Terminal Disclaimer disclaiming the term

of a patent issued from the instant application that extends beyond the term of U.S. Patent No. 6,682,907.

Finally, the Office rejected claims 41 and 51 because it asserted that these claims are unpatentable over claims 21 and 23-26 of co-pending application Serial No. 10/313,038. Applicants traverse this rejection noting that claims 1-35 of Application No. 10/313,038 were canceled in a Preliminary Amendment filed September 30, 2003.

35 U.S.C. § 112

On page 7 of the Office Action, the Office rejected claims 46-49 under 35 U.S.C. § 112, second paragraph. Specifically, the Office asserted that claim 46 is indefinite because it found the phrase "may be" to be non-limiting and to render the phrases following it meaningless. As amended, claim 46 does not include the term "may be." Therefore, claim 46 is not indefinite.

The Office also asserted that claims 47 and 49 are indefinite because of a perceived insufficient antecedent basis for the term "the *gag*, *pol*, and *env* sequences." As amended, claims 47 and 49 indicate that gag, pol, and env sequences are provided by one or more vector(s) in addition to the recombinant vector of claim 41 and, thus, do not require antecedent basis. This amendment is supported on page 7, line 22, through page 8, line 4, of the specification.

Finally, the Office rejected claim 48 because it asserted that this claim depends from itself. As amended, claim 48 depends from claim 47 and is, therefore, definite.

In light of these amendments, Applicants respectfully request that the rejections under 35 U.S.C. § 112, second paragraph, be withdrawn.

35 U.S.C. § 102

On pages 8-9 of the Office Action, the Office rejected claims 41-51 under 35 U.S.C. § 102(b) as being anticipated by WO 97/12622 ("Verma"). The Office asserted that Verma teaches a retroviral vector comprising a *pol* gene. The Office also asserted that the vector taught by Verma has at least one cPPT and at least one cis-acting CTS, which would necessarily induce the formation of a triple-strand DNA structure during reverse transcription of the vector sequence.

Applicants traverse this rejection for claim 41, and for claims 42-46, 48, 50, and 51, which depend on claim 41, because the claimed recombinant vector comprises "**a** polynucleotide." *See* specification at page 5, lines 4-6 ("The invention concerns the use of this triplex sequence **alone or in a vector** to introduce nuclear type sequences to which the triplex sequence is bound into the nucleus of the receiving eukaryotic cell." (emphasis added)). In contrast, the disclosure of Verma involves a combination of a minimum of three vectors. *See* Verma at page 15, lines 21-22. Specifically, Verma teaches that three vectors are required, such as those described in Figure 1, including a transfer vector, a packaging construct, and a pseudotyping ENV plasmid. In contrast, construction of one nucleic acid in the claimed invention is described in the Materials and Methods in the Example of the instant application, which begins on page 23 with the description of the pTRIP-LacZ and pTRIP-EGFP plasmids. Because the claimed invention requires "**a** polynucleotide" and Verma requires three vectors, Verma cannot anticipate the invention.

Furthermore, Applicants traverse the rejection of claim 41, and claims 42-51, which depend on it, because Applicants' invention utilizes a different vector than that

described in Verma to achieve a higher level of nuclear import. The specification of the instant application describes construction of plasmid vectors, pTRIP-LacZ and pTRIP-EGFP, which include the claimed elements cPPT and CTS, on pages 23-24. The specification explains: "The pTRIP-LacZ and pTRIP-EGFP plasmids derive from the pHR'CMVlacZ construction (Naldini et al, 1996)." Specification at p. 23, lines 14-15 (emphasis added). The specification then states: "In order to test the importance of the triplex structure in a vector system, the inventors took as a basis the constructions described in Naldini et al." Specification at page 31, lines 7-8. In fact, the Naldini *et al.* publication describes the same plasmid vectors that are described in Verma, which was cited by the Office.

These vectors differ from those in the instant application, though, because the claimed vectors include additional sequences not found in the constructs described by Naldini. After citing Naldini *et al.*, the instant specification continues by explaining:

> A 184 bp fragment corresponding to the central region of the HIV-1 genome and comprising the cis-acting cPPT and CTS regions responsible for the formation of the triplex during reverse transcription of the HIV was inserted in the ClaI site of the pHR-EGFP and pHR'CMVlacZ plasmids, upstream of the CMV promoter.

Specification at p. 24, lines 5-8 (emphasis added). The specification then continues with a detailed description of the 184 bp fragment with the cPPT and CTS sequences. Independent claim 41, and claims 42-51, which depend from claim 41, each include the elements of the cPPT and CTS region and therefore include elements that are not disclosed or suggested by Verma. Furthermore, the description of the other plasmid

vectors disclosed by the Verma, pCMVΔR8 and pHR'-Clucif, do not include the elements of the cPPT and CTS regions.

In general, the vector described in Verma is a vector with sequences from the *env* and *gag* genes. *See* Example 2. Sequences from the *pol* gene, though, are not described, nor are they a part of the pHR' vector described in Verma. In contrast, the claimed vectors contain sequences from the *pol* gene, specifically the cPPT and CTS sequences. Because Verma does not disclose a vector consisting of "**a** polynucleotide" or one which includes the cPPT and CTS sequences, Verma cannot anticipate the claimed invention. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) in light of Verma be withdrawn.

On pages 9-10 of the Office Action, the Office also rejected claims 41-48, 50, and 51 under 35 U.S.C. § 102(b) as being anticipated by Parolin *et al* (1994) ("Parolin"). The Office asserted that Parolin teaches HIV vectors comprising the pol gene, which include at least one cPPT and at least one CTS cis-acting region, which would necessarily induce the formation of a triple stranded DNA structure during reverse transcription of the vector sequence. Applicants traverse this rejection because Parolin does not recite each and every element of the claimed invention.

Specifically, Parolin requires two different plasmids, one which expresses the *gag*, *pol*, *tat*, and *vif* gene, and the other which expresses the *env* and *rev* gene. In contrast, the embodiments claimed in claims 41-46 and 50-51 are drawn to "**a** polynucleotide." *See*, specification at page 5, lines 4-6.

In addition, Parolin does not teach that the cPPT or CTS sequences are required as in the vectors claimed in claims 41-51. Instead, Parolin indicates that *gag*

sequences increase the efficiency of gene transfer, while the addition of *pol* sequences to the *gag* sequences does not increase the efficiency any further. *See*, Parolin at page 3892, paragraph bridging columns 1 and 2 ("The v0 RSN vector, which lacks gag sequences, exhibited an average titer of $10^{0.7}$. Increased efficiency of gene transfer was associated with the inclusion of additional *gag* sequences in the vectors. . . . The inclusion of more than 653 nucleotides of *gag-pol* sequences in the vectors v1216 RSN, v1864 RSN, and v2731 RSN did not further improve the efficiency of gene transfer relative to that of the v653 RSN vector.")

Because neither Parolin nor Verma disclose each and every element of the claimed invention, neither reference can anticipate it. Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. § 102(b) be withdrawn.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

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By: _____

Deborah Katz
Reg. No. 51,863
Telephone: (202) 408-4382
Facsimile: (202) 408-4400
E-mail: deborah.katz@finnegan.com